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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,217

07/15/2005

Takao Shimizu

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05/19/2009

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,217	<b>Applicant(s)</b> SHIMIZU ET AL.	
	<b>Examiner</b> RUIXIANG LI	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16, 17 and 19-39 is/are pending in the application.  
     4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 17, 19-25, 29 and 33-36 is/are rejected.
- 7) ☒ Claim(s) 26-28, 30-32, 37-39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

Applicant's amendment filed on 03/31/2009 has been entered. The Declaration of Satoshi Ishii under 37 C.F.R. 1.132 has been received and considered. Claims 22-39 are added. Claims 16, 17, and 19-39 are pending. Claims 17 and 19-39 are under consideration. Claim 16 is withdrawn from consideration.

Applicants submit that amended claim 16 shares a special technical feature with claims 17 and 22 and thus should be examined in the present application. Applicants' argument has been fully considered, but is not deemed to be persuasive because claim 16 does not shares the special technical feature of "screening for an agonist or an antagonist to the LPA receptor". Thus, unity of invention is lacking and restriction is appropriate.

### **Withdrawn Objections and/or Rejections**

The rejection of claims 17 and 19-21 under 35 U.S.C. §112, second paragraph is withdrawn in view of amended claims.

### **Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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(ii). Claims 17 and 19-21 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The basis for the rejection is set forth in the office action mailed on 11/04/2008. New claims 22-25 and 34-36 are also rejected on the same basis.

(iii). Response to Applicants' argument

On page 14, the 1<sup>st</sup> paragraph, Applicants argue that the examiner indicated that if the claims were amended to recite "wherein said G protein-coupled receptor p2y9 comprises seven transmembrane regions", the written description rejection would be withdrawn. The examiner disagrees. This is because "seven transmembrane regions" does not represent a particular structure that confers a specific functional activity, such as LPA-binding activity. Moreover, the specification merely discloses the human p2y9 protein of SEQ ID NO: 1 that binds LPA, but fails to disclose any other p2y9 protein variants that bind LPA, or a function/structure relation. Thus, the written description rejection must be maintained.

On page 14, the 2<sup>nd</sup> paragraph, Applicants present the Declaration of Satoshi Ishii under 37 C.F.R. 1.132. The declaration provides evidence showing mouse p2y9 (also known as GPR23), which shares 98.1% sequence homology with SEQ ID NO: 1 of the present invention, binds LPA. Satoshi Ishii concludes that allele variants with at least 95%

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homology to human p2y9 will bind LPA. Applicants' argument has been fully considered, but is not deemed to be persuasive. The Declaration of Satoshi Ishii under 37 C.F.R. 1.132 has been fully considered but is insufficient to overcome the written description rejection because there is no evidence provided showing that Applicants were in possession of the recited genus of p2y9 proteins that bind to lysophospholipid at the time the application was filed.

On page 15, the 2<sup>nd</sup> paragraph and the 3<sup>rd</sup> paragraph, Applicants cite excerpt from *Molecular Biology of the cell*, Third Edition, and argue that a G-protein coupled receptor having seven transmembrane regions is firmly fixed to the cell membrane and forms a ligand binding domain outside the cell, which establishes the structure which peculiarly binds to its corresponding ligand. This has been fully considered, but is not deemed to be persuasive because "seven transmembrane regions" does not give rise to a particular ligand-binding or other activity and does not represent a structure/function relation.

On page 15, the 3<sup>rd</sup> paragraph, Applicants cite the publication of Joost and Methner and argue that G protein coupled receptors are classified in the same class based on their sequence similarity in the evolutionary tree. Applicants argue that this document indicates that even different receptors generally recognized similar ligands if they are closely related in the evolutionary tree. As such, allele receptors with at least 95% homology will recognize the same ligand.

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Applicants' argument has been fully considered, but is not deemed to be persuasive because while Joost and Methner teach that knowledge of the phylogenetic relationship of orphan receptors to receptors with known ligands could facilitate ligand identification (Abstract and conclusion), Joost and Methner do not teach allele receptors with at least 95% homology will recognize the same ligand.

In fact, p2y9 and p2y5 are closely related in the evolutionary tree (see Fig. 1 of the instant disclosure), p2y9, not p2y5, exhibited a specific reactivity against LPA (page 25, the 2<sup>nd</sup> paragraph of the instant specification). On the other hand, while p2y9 is remotely related to EDG family (edg-2 and edg-4) in the evolutionary tree (see Fig. 1 of the instant disclosure; page 5, the 2<sup>nd</sup> paragraph of the instant specification), both p2y9 and edg-2/edg-4 function as a receptor for LPA (bridging the bottom of page 3 and the top of page 4 of the instant specification). The publication of the inventors of the instant application also supports the observation (Noguchi et al., J. Biol. Chem. 278:25600-25606, July 11, 2003).

### **Claim Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 21, 25, 29, and 33 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 21, 25, 29, and 33 are indefinite because they recite “wherein said candidate compound is an inhibitor of carcinoma cell invasion”. If a candidate compound that acts as an agonist of G protein-coupled receptor p2y9 functions as an inhibitor of carcinoma cell invasion, a candidate compound that acts as an antagonist of G protein-coupled receptor p2y9 would not function as an inhibitor of carcinoma cell invasion, and vice versa.

### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

May 13, 2009